

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Nasal intermittent positive ventilation (NIPPV) or conventional mechanical ventilation for treatment of neonatal respiratory failure

Protocol summary

Summary

Our purpose is to compare two modalities; Nasal intermittent positive ventilation (NIPPV) and conventional ventilation (CV) for treatment of respiratory failure in preterm neonates. This prospective clinical trial performs on 50 patients with gestational age less than 35 weeks and Birth Weight less than 2500 grams that have continuous positive airway pressure (CPAP) failure and admitted in NICU of Alzahra and Shahid Beheshti hospitals in Isfahan that they excluded by nasopharyngeal pathology; coanal atresia; cleft/lip palate; major anomalies especially thoracic or cardiac anomalies; intra ventricular hemorrhage (IVH) grade 3 or 4 on admission; their parents refuse to participate in the research project. . The randomization is performed applying minimization technique with respect to baby's gender and Birth weight and the newborns will be divided into two groups; NIPPV and CV. We will also assess the incidence of complications such as pneumothorax, intra ventricular hemorrhage (IVH), bronchopulmonary dysplasia (BPD), necrotizing enterocolitis (NEC) and patent ductus arteriosus (PDA) in our trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011412132N1**

Registration date: **2013-03-24, 1392/01/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-03-24, 1392/01/04

Registrant information

Name

Babak Nekooie

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1627 3077

Email address

b_nekooie@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2012-11-28, 1391/09/08

Expected recruitment end date

2013-04-20, 1392/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Nasal intermittent positive ventilation (NIPPV) or conventional mechanical ventilation for treatment of neonatal respiratory failure

Public title

Nasal intermittent positive ventilation (NIPPV) or conventional mechanical ventilation for neonatal respiratory failure

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: gestational age less than 35 weeks; birth weight less than 2500 grams; CPAP failure (Fio2 more than 60% and maximum CPAP 8 cmH2O and/or PH less than 7.2 and PCO2 more than 60 and/or more than 3

episodes apnea with bradycardia (heart rate less than 80 per minute in 20,31,35 hours). exclusion criteria: nasopharyngeal pathology; coanal atresia; cleft/lip palate; major anomalies especially thoracic or cardiac anomalies; intra ventricular hemorrhage (IVH) grade 3 or 4 on admission; their parents refuse to participate in the research project.

Age

To **1** year old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences

City

Isfahan

Postal code

81577_2342

Approval date

2012-11-28, 1391/09/08

Ethics committee reference number

391369

Health conditions studied**1****Description of health condition studied**

Respiratory failure of newborns

ICD-10 code

p28.5

ICD-10 code description

Respiratory failure of newborns

Primary outcomes**1****Description**

response to treatment

Timepoint

during hospitalization and using NIPPV and conventional mechanical ventilation

Method of measurement

comparing survival rates according to serial arterial blood gas (ABG) sampling.

Secondary outcomes**1****Description**

incidence of bronchopulmonary dysplasia (BPD)

Timepoint

during hospitalization and using NIPPV and conventional mechanical ventilation

Method of measurement

Taking CXR on admission and weaning

2**Description**

incidence of intra ventricular hemorrhage (IVH)

Timepoint

during hospitalization and using NIPPV and conventional mechanical ventilation

Method of measurement

cranial ultrasonography on admission and deterioration of clinical status

3**Description**

incidence of patent ductus arteriosus (PDA)

Timepoint

during hospitalization and using NIPPV and conventional mechanical ventilation

Method of measurement

Echocardiography on admission and deterioration of clinical status

4**Description**

incidence of necrotizing enterocolitis (NEC)

Timepoint

during hospitalization and using NIPPV and conventional mechanical ventilation

Method of measurement

According to Bell's criteria

5**Description**

incidence of pneumothorax

Timepoint

during hospitalization and using NIPPV and conventional mechanical ventilation

Method of measurement

Taking CXR on admission and deterioration on clinical status

Intervention groups

1

Description

Nasal intermittent positive pressure ventilation (NIPPV) involves giving continuous positive airway pressure (CPAP) to the infant in the intermittent mandatory ventilation (IMV) mode.

Category

Treatment - Devices

2

Description

Conventional mechanical ventilation is a method of ventilation that patient have endotracheal intubation and and connect to ventilator by that.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Babak Nekooie

Street address

Alzahra hospital, Sofe blvd, Isfahan

City

Isfahan

2

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Babak Nekooie

Street address

Shahid Beheshti hospital, Motahari blvd, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Zohreh Badiei

Street address

Isfahan University of Medical Sciences, Hezarjarib Ave, Isfahan

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Babak Nekooie

Position

fellowship in neonatology

Other areas of specialty/work

Street address

Alzahra hospital, Sofe blvd, Isfahan

City

Isfahan

Postal code

Phone

+98 31 1625 5555

Fax

Email

b_nekooie@resident.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Zohreh Badiei

Position

Neonatology, Assistant professor

Other areas of specialty/work

Street address

Alzahra hospital, sofe blvd, Isfahan

City

Isfahan
Postal code
Phone
+98 31 1625 5555
Fax
Email
badiei@med.mui.ac.ir
Web page address
www.mui.ac.ir

Postal code
Phone
+98 31 1625 5555
Fax
Email
badiei@med.mui.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Zohreh Badiei
Position
Neonatologist, Assistant professor
Other areas of specialty/work
Street address
Alzahra hospital, Sofe blvd, Isfahan
City
Isfahan

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty